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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/619,584    07/19/00    BERNARDON

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EXAMINER

BAZILS

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

09/19/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/619,584**

Applicant(s)  
**Bernarden et al.**

Examiner  
**Sabiha Qazi**

Art Unit  
**1616**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 22, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-32 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13, and 16-23 is/are rejected.
- 7) ☒ Claim(s) 14, 15, and 24-32, 29-32 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

***Office Action on Merits***

Claims 12-32 are pending.

Applicant's response filed in paper no. 9 is hereby acknowledged. Claims rejected over Apfel et al. (J. Biol. Chem. (1995), 270(51), 30765-72) is withdrawn because arguments were found persuasive. Non elected invention must be canceled while responding to this action. Elected invention is drawn to compounds and composition. Examiner will combine method claim if written in a form that it should have a full support in specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12, 13, 19, 20, 21, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Obushak, N. D. Et al. (DN 113:152173, HCAPLUS; Abstract of Zh. Org. Khim. (1990), 26(4), 873-80). See abstract and compound of RN 62806-31-9P .
2. Claims 12, 13, 19, 20, 21, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Krutosikova, A. et al. (DN 84:58390, HCAPLUS; abstract of Collect. Czech., Chem. Commun. (1975), 40(11), 3362-9). See abstract and compound of RN58110-44-4 and 58110-55-7P.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

**Basis of Rejection**

The method of use and pharmaceutical compositions for the use to treat various kinds of diseases is broad. Specification does not support the use of the compounds for variety of diseases listed in claims. For example the terms "cancerous and precancerous disease conditions" in claims is broad and specification is not enabled for the treatment of all the diseases as claimed.

There is no drugs which is broadly effective against all forms of cancer, (see Carter S.K. et al. Chemotherapy of Cancer, pages 364 and 365; second edition, John Wiley & sons, New York, 1981, appendix C). See table on pages 364 and 365 where the interaction of different drugs on various type of

cancer are listed. It is clear from the data that each drug has different interactions with different types of tumors i.e. one drug cannot treat all type of cancer.

The claims should be limited to certain types of cancer which is supported in specification.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered [In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)]:

- 1) Breadth of claim
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level of predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**1) The nature of the invention:**

**1) The nature of the invention:** The invention is directed to compounds and method of treatment of various kind of diseases for example treatment of insulin dependent diabetes, arteriosclerosis, cancerous and precancerous states, arthritis, hypertension etc. (Listed in claim 18).

**2) The predictability or lack thereof in the art:** There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

Claims are drawn to the treatment of cancerous disease and precancerous disease along with a list of diseases said to be useful for the treatment by the instant compounds.

The specification does not provide enablement for the treatment of cancer generally. No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end.

Nearly all anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception.

**3) The amount of direction or guidance present:** The disclosure does not describe the method of use of the compounds of the instant invention for the treatment of various types of diseases as for example described in claim 18 and other claims. How precancerous condition can be treated?. There is no support for all the cancerous diseases as claimed.

**4) The quantity of experimentation needed:** Since the are of unknown breadth and since there is a lack of a guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is claimed in claim 28, which group is considered is to be interrupted by an oxygen atom or sulfur atom.

Claims 14, 15 and 24-27, 29-32 are objected to for containing non-elected invention. When Ar is © or (d) was examined in this application. For example claim 31 and 32 contain compound which is non-elected. It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this office action. A typing error was noted by the Examiner in second last line of claim 15, "e" should be deleted from "reing".

#### **Telephonic Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**Sabiha N. Qazi, Ph.D.**

**Primary Examiner**

**Art Unit 1616**

**9/5/01**